

REMARKS

Summary of the Invention

The invention features methods for assaying a compound for its ability to affect cell division by determining whether the compound affects the interaction between an isolated estrogen receptor beta (ER) polypeptide and mitosis arrest deficient 2 (MAD2), or a binding fragment thereof.

The Office Action

Claims 1-8 are pending. Claims 4, 5, 7, and 8 are withdrawn from consideration. Claims 1-3 and 6 are rejected under 35 U.S.C. § 112, first and second paragraph, for an inadequate written description and indefiniteness, respectively. Claims 1, 3, and 6 are rejected under 35 U.S.C. § 102(b) for anticipation by Iafrati et al. (Nature Medicine 3:545-548, 1997; hereinafter "Iafrati"). Finally, the amendment to the specification and sequence listing, submitted on September 26, 2002, is objected to under 35 U.S.C. § 132 for introducing new matter. By this reply, Applicant amends the specification, amends claim 1, adds new claims 13 and 14, and addresses each of the Examiner's rejections and objections below.

Support for the Amendment

Claim 1 has been amended to clarify the method steps. Support for the addition of new claims 13 and 14 is found in the specification on, e.g., page 9, line 1, through page 10, line 10. No new matter is added by the amendment.

Interview with the Examiner

Applicant would like to thank the Examiner for his helpful comments during an Interview conducted on June 4, 2004, in which the present rejections were discussed.

Objection to the Specification and Sequence Listing

The amendment to the specification and the amendment to the paper sequence listing submitted in the reply to Office Action on September 26, 2002 are objected to under 35 U.S.C. § 132. The Examiner states that the amendments introduce new matter and must be cancelled. In response, Applicant submits an amendment to the specification that cancels the subject matter that was objected to by the Examiner. Applicant also submits a new sequence listing consisting of four pages and including SEQ ID NOs: 1-4, as originally filed. Therefore, this objection should now be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-3 and 6 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner states that the terms “estrogen receptor beta,” “mitosis arrest deficient 2,” “ER beta,” “MAD2,” and “GST-ER β ” are ambiguous because the metes and bounds of the terms have no structural limitations.

During the telephonic interview of June 4, 2004, Applicant argued that these terms were well known in the art prior to the filing of the present application and would be clearly understood by one skilled in the art without the need for additional structural limitations. The Examiner acknowledged Applicant’s argument and agreed to withdrawn this rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-3 and 6 are rejected under 35 U.S.C. § 112, first paragraph, for an inadequate written description. During the telephonic interview of June 4, 2004, the Examiner agreed to withdraw this rejection as well.

Rejections under 35 U.S.C. § 102

Claims 1, 3, and 6 are rejected under 35 U.S.C. § 102(b) for anticipation by Iafrati. The Examiner states that Iafrati teaches all of the elements of present claims 1, 3, and 6 because Iafrati discloses an effect on cell division when vascular cells, which express estrogen receptor beta and inherently express MAD2, are treated with estradiol.

During the telephonic interview of June 4, 2004, Applicant argued that Iafrati fails to teach or suggest a method that includes determining an effect on ER β /MAD2 complex or complex formation in the presence of a test compound. The Examiner agreed, but requested that Applicant amend claim 1 to clarify the determination step (b). In response, Applicant submits an amendment to claim 1 that satisfies the Examiner's request. Therefore, this rejection can be withdrawn.

CONCLUSION

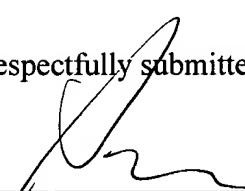
Applicant submits that the claims are in condition for allowance, and such action is respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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